EBI Electro Biology

Enhancing Bone Healing through Applied Science

APR - 9 1997

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510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety and Effectiveness for the EBI SpineLink™ System is provided as required per Section 513(I)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** Electro-Biology, Inc.
6 Upper Pond Road
Parsippany, NJ 07054

Contact Person: Jon Caparotta
Telephone: (201) 299-9022

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2. **Proprietary Name:** EBI SpineLink™ System
Common Name: Posterior pedicle spinal system
Classification Name: Spondylolisthesis Spinal Fixation Device System (Proposed)

3. **Predicate or legally marketed devices that are substantially equivalent:**

- Webb-Morley Spine System - Electro-Biology, Inc.
- TSRH® Spinal System - Sofamor Danek
- Dyna-Lok® Spine System - Sofamor Danek
- Isola® Spine System - AcroMed Corporation
- VSP® Plating System - AcroMed Corporation
- KSF Spinal Fixator - Tornier SA

4. **Description of the device:** The EBI SpineLink™ System is a posterior pedicle system consisting of fixed and polydirectional pedicle/sacral screws (available in diameters from 5.5 to 7.5 mm), various types of interconnecting links, lock nuts, and different types of washers.

Intended Use: The EBI SpineLink™ System (severe spondylolisthesis indication) is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. The screws of the system are limited to L3- S1 or iliac screw fixation.

5. **Materials:** The components of the system are manufactured from Ti-6Al-4V ELI per ASTM F136. The components will be available with and without TiN coating.

6. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between EBI SpineLink™ System and other currently marketed spinal systems. It is substantially equivalent* to the predicate devices in regards to intended use, materials and function. Bench testing comparing the system to a predicate system demonstrated that the device complies with applicable standards and meets all of its functional requirements.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]